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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,826	VERFAILLIE ET AL.	
	Examiner	Art Unit	
	CHANG-YU WANG	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-13* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 3/29/10 is acknowledged. Claims 3-4 are cancelled. Claims 1, 2 and 5-13 are pending in this application. Claim 12 is withdrawn with traverse (filed on 11/19/07) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/19/07.

2. Claims 1-2, 5-11 and 13 are under examination with respect to bone marrow and dopaminergic neurons in this office action.

3. Applicant's arguments filed on 3/29/10 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Maintained

In view of the amendment filed on 3/29/10, the following rejections are maintained.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-9, 11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/086073 (Studer et al., published Oct 31, 2002, cited in office action mailed 10/18/07) in view of US2003/0211605 (Lee et al., published Nov 13, 2003, priority May 1, 2000). The rejection is maintained for the reasons made of record and the reasons set forth below.

Claims 1-2, 5-9, 11 and 13 are drawn to a method for inducing stem cells to differentiate into neuronal cells comprising a) culturing said stem cells with bFGF, b) culturing the cells of step a) with FGF8 and SHH, c) culturing the cells of step b) with BDNF and d) co-culturing the cells of step c) with astrocytes, wherein the cells are cultured according to steps a) through d) for at least seven days at each step. Dependent claims are directed to different stem cells.

On p. 4-5 of the response, Applicant argues that it cannot predict that the phenotype produced by exposing cells to the factors simultaneously will be the same as the phenotype produced by exposing cells to the factors sequentially as support by Dr.

Verfaillie's declaration. Applicant argues that the examiner provides no scientific evidence to rebut the statements of Dr. Verfaillie's regarding different approaches. Applicant's arguments have been fully considered but they are not persuasive.

In response, although the instant method recites adding bFGF, FGF8, SHH and BDNF sequentially, the claimed method is only directed to inducing neuronal differentiation not directed to specifically defined proportions of the specific types of neurons. Note that the claimed method and the cited references are directed to the same goal (neuronal differentiation from stem cells) using the same materials (bFGF, FGF8, SHH and BDNF). The claimed method is directed to inducing neuronal differentiation using the same growth factors (bFGF, FGF8, SHH and BDNF) and the same ES cells and similar culture duration, which are taught by the cited references. Although the claimed method alters the way of adding growth factors in the methods of Studer and Lee, and phenotypical cell types may have different proportions during the recited culturing procedures, at the end of the steps, the result of neuronal differentiation from stem cells including dopaminergic, serotonergic and GABAergic neurons is expected as taught by Studer and Lee (see p.9, [0125], p. 9, [0128]; p. 14, example 5,in particular).

On p. 5-6 of the response, Applicant argues that it is an erroneous reason to dismiss Dr. Verfaillie's declaration based on no side-by-side comparisons to demonstrate that cell types generated from sequential addition of growth factors are different those that are simultaneously exposed to the same growth factors. Applicant

argues that obviousness is based on motivation and expectation of success and Dr. Verfaillie's declaration explains what a skilled artisan would have expected different results from simultaneous and sequential exposure to the same factors. Applicant further acknowledges that a skilled might have tried different modifications but Applicant argues that no guidance regarding the specific factors, sequence and duration as claimed. Applicant's arguments have been fully considered but they are not persuasive.

In response, since Applicant's position is that the claimed method that includes sequential exposure to the same growth factors would be different from the results generated from simultaneous exposure to the same factors, Applicant is required to provide data to support the difference between the prior art and the instant as claimed. Note that

> The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

In addition, given the examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in KSR International Co. V. Teleflex Inc. 82 USPQ2d 1385 (2007) and the Examination Guidelines set forth in the Federal Register (Vol. 72, No. 195, October 10, 2007) and incorporated recently into the MPEP (Revision 6, September 2007), the following rationales to support rejection under 35 U.S.C. 103(a) are noted:

A) Combining prior art elements according known methods to yield predictable results.

B) Simple substitution of one known element for another to obtain predictable results.

C) Use of known technique to improve similar products in the same way.

D) Applying known technique to a known product ready for improvement to yield predictable results.

E) "Obvious to try" --- choosing form a finite number of identified, predictable solutions, with a reasonable expectation of success.

F) Some teachings, suggestion, or motivation in the prior art that would lead to one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

In this case, the neuronal differentiation results derived from simple substitution of simultaneous addition of the same growth with sequential addition of the same growth factor are expected. In addition, it is also obvious to try and modify the order of adding the same growth factors because the stem cells are also expected to be differentiated into neuronal after sequential treatment of the same growth factors. Note that obviousness is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR International Co. V. Teleflex Inc. 82 USPQ2d 1385 (2007). From the combined teachings of the references, it is apparent that one of ordinary skill in the art

would have had a reasonable expectation of success in producing the claimed invention.

On p. 6 of the response, Applicant's argues that the evidence shown in Dr. Verfaillie's need not be directed to the same cells. Applicant's arguments have been fully considered but they are not persuasive.

In response, Applicant's arguments are contradictory to Applicant's own position as stated in Dr. Verfaillie's declaration because Dr.Verfaillie's declaration states that different phenotype neural cells will respond to growth factors differently. If this statement is true, then the evidence based on the cited the cited reference (Snykers et al. Toxicological science. 2006, 94: 330-341) that is directed to hepatic cells will act differently in response to growth factors and differentiate into different cells and thus cannot be compared with stem cells differentiated into neurons. Thus, the evidence cited in the Dr.Verfaillie's declaration is not relevant to the instant applications and is insufficient to overcome the rejection.

On p. 7 of the response, Applicant argues that the citation of *Sinclair & Carroll, In re Aller, In re Kerkhoven, In re Crockett and Ex parte Quadranti* is inapt because the instant case does not go to the situation where a known material was used, Applicant has not explored optimum or workable range and the claimed method is not directed to combing two compositions to form a third composition. Applicant's arguments have been fully considered but they are not persuasive.

Note that although the instant application is not directed to a composition, the above citations are proper because the instant case is based on the same known materials (the functions and the known effects of each growth factor on stem cells) and known culture protocols for neuronal differentiation from stem cells to modify and optimize the culture protocols. Thus, the results of neuronal differentiation from stem cells are expected. It is noted that the instant claims are not directed to generation of different proportions of different neuronal cell types.

On p. 8-9 of the response, Applicant argues that Lee teaches that SHH and FGF8 may be added at Stages I and II but less effective in generating dopaminergic neurons. Applicant argues that if SHH and FGF8 were added at Stages I and II, then it would be prior to the addition of bFGF. Applicant argues that SHH and FGF8 were added in the expansion medium at Stage IV and neuronal differentiation is induced by removal of bFGF or EGF so there are at least bFGF and SHH and FGF8 at stage IV expansion. On p. 10-18 of the response, Applicant summarizes the teachings of Lee and Studer. On p. 15 of the response, Applicant argues that bFGF, FGF8 and SHH at stage IV are all administered together for 6-7 days but does not teach the claimed combination of factors, sequence and duration protocol and Studer does not compensate the deficiency of Lee. On p. 18 of the response, Applicant argues that Studer does not discuss duration except for stages III (9-16days). Applicant argues that there is no motivation to alter the Studer and Lee's procedures by culturing for seven

days at each step to practice the claimed invention. Applicant's arguments have been fully considered but they are not persuasive.

In response, Applicant cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to Applicant's arguments regarding sequence, combination of factors and duration, although the instant method recites adding bFGF, FGF8, SHH and BDNF sequentially, the claimed method is only directed to inducing neuronal differentiation not directed to specifically defined proportions of the specific types of neurons. It is noted that the claimed method and the cited references are directed to the same goal using the same materials. The claimed method is directed to inducing neuronal differentiation using the same growth factors (bFGF, FGF8, SHH and BDNF) and the same ES cells, which are taught by the cited references. Although the claimed method alters the way of adding growth factors, and phenotypical cell types may have different proportions during the recited culturing procedures, the end result of neuronal differentiation is expected and to generate neurons including dopaminergic, serotonergic and GABAergic neurons as in claim 11.

In addition, Lee teaches that addition of SHH and FGF8 at the early stages is less effective (see p. 9, [0126], in particular), which provides motivation to add SHH and

FGF8 after addition of other growth factor that induce proliferation such as bFGF. Furthermore, Lee teaches that the CNS precursor cells (including CNS stem cells and embryoid cells/neurospheres) are expanded in the CNS proliferation medium in the presence of bFGF or EGF for about 6 to 7 days (see p. 9, [0123]-[0124], in particular). Lee also teaches that the culture medium may also be supplemented with SHH and FGF8 because SHH and FGF8 are more effective to increase the generation of dopaminergic neurons (see p.9, [0125], in particular). Moreover, Lee teaches that neuronal differentiation is induced by withdrawal of at least one neurological agent, such as bFGF in the culture medium in the presence of the factors to enhance the generation of dopaminergic neurons for five to 6 days (see p. 9, [0128]; p. 14, example 5, in particular).

Furthermore, Studer teaches that in order to generate astrocytes, before adding SHH and FGF8 into the culture medium, the ES cells are proliferated and cultured in a culture medium in the presence of bFGF (see p. 5, paragraphs 16-17; p. 26, paragraph 78, in particular). Studer teaches that to enhance dopaminergic and serotonergic neurons, ES cells are cultured in the proliferation culture medium in the presence of FGF8 and SHH for 6-9 days (see p. 28, paragraph 85; p. 29, paragraph 86, in particular). Studer also teaches that expanded ES cells from stage IV are induced to neuronal differentiation in the culture medium in the presence of BDNF and in the absence of SHH and FGF8 for 4-10 days (see p. 26, paragraph, 78; p.29, paragraph 87, in particular).

Both Lee and Studer do teach the use of different growth factors separately because each different growth factor can enhance different cell populations. For example, Lee and Studer teach that bFGF can be used to expand ES cells, and FGF8 and SHH can be used to increase the generation of dopaminergic neurons. In addition, the culture medium in the presence of bFGF and in the absence of FGF8 and SHH can increase astrocyte generation. Further, the culture medium in the presence of BDNF and in the absence of FGF8 and SHH can induce neuronal differentiation. Thus, it would have been obvious to add different growth factors sequentially. The person would have been motivated to do so because each different growth factor can increase specific type cell populations. In this case, the addition of bFGF is to induce ES cell expansion and can enhance astrocyte generation for neuronal survival. The addition of FGF8 and SHH to the expanded ES cells after the exposure of bFGF can enhance the generation of dopaminergic and serotonergic neurons. The addition of BDNF after the exposure of FGF8 and SHH can induce neuronal differentiation.

In response to Applicant's arguments regarding at least 7 days for each step, although Studer and Lee do not explicitly teach at least 7 days for each step, the claimed procedures and incubation time for each step are obvious over the cited reference because the incubation time for each step is within or overlaps with the claimed incubation. In addition, as previously made of record, it is known in the art that neural cells (neural progenitor/stem cells) co-cultured with astrocytes can enhance neuronal survival and differentiation. Thus, it has been obvious to combine the

teachings of Studer and Lee to achieve and practice the claimed invention because the results of dopaminergic and serotonerigc neuronal differentiation are expected. Note that

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie*case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990), See MPEP 2144.05-I.

"a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)" See MPEP 2144.05-I.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105USPQ 233, 235 (CCPA 1955)" See MPEP 2144.05-II.

Taken together, the claimed method of sequentially adding growth factors to ES cells is obvious over the cited references because Lee and Studer do provide a motivation and an expectation of success to add growth factors sequentially. Lee and Studer teach that each different growth factor used separately can enhance different cell populations. For example, ES cells incubated with bFGF alone with no FGF8 and SHH will increase ES cell proliferation and increase astrocyte generation, and astrocytes have been shown to enhance neuronal survival. In addition, expanded ES cells incubated with FGF8 and SHH will increase the generation of dopaminergic and serotonergic neuronal lineage. Finally, ES cells treated with FGF8 and SHH and further incubated with BDNF without bFGF or FGF8 and SHH can be induced into dopaminergic neurons. Thus, a skilled artisan would have been motivated and would have expected success to add growth factors sequentially to expand specific neuronal populations.

5. Claims 1-2, 5-11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/086073 (Studer et al., published Oct 31, 2002, cited in office action mailed 10/18/07) in view of US2003/0211605 (Lee et al., published Nov 13, 2003, priority May 1, 2000) as applied to claims 1-7, 9, 11 and 13 above, and further in view of Song et al. (Methods in Mol. Biol. 2002. 198: 79-88). The rejection is maintained for the reasons made of record and the reasons set forth below.

Claims 1-2, 5-11 and 13 are drawn to a method for inducing stem cells to differentiate into neuronal cells comprising a) culturing said stem cells with bFGF, b) culturing the cells of step a) with FGF8 and SHH, c) culturing the cells of step b) with BDNF and d) co-culturing the cells of step c) with astrocytes, wherein the cells are cultured according to steps a) through d) for at least seven days at each step. Dependent claims 5-11 are directed to different stem cells.

On p. 19 of the response, Applicant argues that Song does not compensate the deficiencies of Suder and Lee and is directed to any differentiation protocol but teaching stem cells. Applicant's arguments have been fully considered but they are not persuasive.

In contrast to Applicant's arguments, for the reasons as set forth above, Studer and Lee do render the claimed invention of the claims 1-2, 5-11 and 13 obvious.

Although Studer and Lee do not teach multipotent adult progenitor cells and bone marrow as recited in instant claims 7-10, Song et al. teach a method of culturing and differentiating bone marrow and umbilical cord blood cells into neural progenitor cells and neurons in a DMEM/F12 medium comprising FGF-2/bFGF, EGF, transferrin, insulin, putrescine, progesterone, selenium, trans-retinoic acid, BDNF and NGF (see p. 80, in p articular). Song et al. also teach culturing human and mouse bone marrow and human umbilical cord cultures (p. 82-83). The bone marrow and umbilical cord blood cells encompass stem cells and nonhematopoietic progenitor cells from bone marrow are mesenchymal stem cells or bone marrow stromal cells as taught by Song et al. (p.79), which meet the limitations of multipotent adult progenitor cells (MAPCs) and bone marrow as recited in instant claims 7-10. Thus, it is obvious to differentiate stem cells that are derived from multipotent adult progenitor cells (MAPCs) and bone marrow into neurons by using the culture conditions of WO02/086073 and US2003/0211605.

Note that Song was cited for the subject matter of differentiating bone marrow and umbilical cord blood cells into neural progenitor cells and neurons. Applicant cannot show non-obviousness by attacking each individual reference when the rejection is based on the teachings of the combined references.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 8 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The rejection is maintained for the reasons made of record.

On p. 19-20 of the response, Applicant argues that the recitation "cells that are not embryonic stem cells.....can differentiate into at least one cell type of each of the endodermal, ectodermal and mesodermal embryonic lineages" is not new matter because the parent application (US Patent No. 7015037) was incorporated into 11/238234, 10467963 and the instant applications and the examiner did not reject the claims based on inadequate written description in prosecution of 11/238234 or 10/467963. Applicant further cites paragraph spanning pages 8 and 9 and the first paragraph of page 9 of 11/238234 in support of the arguments. Applicant's arguments have been fully considered but they are not persuasive.

In response to Applicant's argument that no new matter was raised during the prosecution of 11/238234 or 10/467963, Applicant's arguments have been noted. However, each application is judged by its own merits.

In this case, the examiner asserts that the incorporated references do not teach the limitation "cells that are not embryonic stem cells, embryonic germ cells, or germ cells and can differentiate into at least one cell type of each of the endodermal,

ectodermal and mesodermal embryonic lineages." as recited in instant claims 7-8 because the cited pages 8-9 of 11/238234 only teaches "an isolated multipotent non-embryonic, non-germ cell line cell that expresses transcription factors Oct3/4, REX-1 and ROX-1" and states that "the cell may have the capacity to be induced to differentiate to form at least one differentiated cell type of mesodermal, ectodermal and endodermal origin" see p. 8-9 of the specification of 11/238234 (same with 10/048757).

Note that as previously made of record; the scope of the cells that express specific markers (transcription factors) disclosed in 10/048757 is different from that of the cells with no defined markers as recited in instant claims. The isolated multipotent non-embryonic, non-germ cell line cells recited in 11/238234 or 10/048757 are limited to specific non-embryonic, non-germ cell line cells that expresses transcription factors Oct3/4, REX-1 and ROX-1. However, the limitation "cells that are not embryonic stem cells, embryonic germ cells, or germ cells and can differentiate into at least one cell type of each of the endodermal, ectodermal and mesodermal embryonic lineages" recited in the instant claims is not limited to specific cells that express specific transcription factors; and thus the scope of the instant claims is different from that of the cited incorporated references.

Thus, the limitation of "cells that are not embryonic stem cells, embryonic germ cells, or germ cells and can differentiate into at least one cell type of each of the endodermal, ectodermal and mesodermal embryonic lineages" recited in instant claims was not clearly disclosed in the specification and claims as originally filed. The

limitation recited in the present claims introduces new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. Note that

"Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement." See MPEP §2173.05

Accordingly, the rejection of claims 7 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement due to new matter is maintained.

Conclusion

7. NO CLAIM IS ALLOWED.

8. This application contains claim 12 drawn to an invention nonelected with traverse in the reply filed on 11/19/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang
June 7, 2010

/Christine J Saoud/
Primary Examiner, Art Unit 1647